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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,559	10/03/2001	E. Marlowe Goble	GOBLE-1	1489
7590	12/01/2004		EXAMINER	
Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02451-1941			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/970,559	GOBLE, E. MARLOWE
	Examiner	Art Unit
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 September 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2 and 4-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2, 4-21 and 23-29 is/are rejected.

7) Claim(s) 22 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 October 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2004 has been entered.

Response to Amendment

2. Applicant's cancellation of claims 1 and 3 in the reply filed on September 20, 2004 is acknowledged.
3. Applicant's addition of claims 5-29 in the reply filed on September 20, 2004 is acknowledged.

Drawings

4. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore,
 - a. The "*endosteal guide*" having "*an interior surface and an exterior surface, the interior surface bounding a channel extending through the endosteal guide such that the flexible filament*

may pass through the channel of the endosteal guide" (see claim 16, lines 2-4) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 4, 7, and 26 are objected to because of the following informalities:

a. Regarding claim 4, please substitute "a distal end and" (see line 4) with --a distal end,--. Appropriate correction is required.

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- b. Regarding claim 4, please substitute "of said flexible filament relative to said bone fixation element" (see lines 29-30) with --of said bone fixation element relative to said flexible filament-- (compare to claim 12, lines 9-10). Appropriate correction is required.
- c. Regarding claim 7, please delete "further" (see line 1). Appropriate correction is required.
- d. Regarding claim 26, please substitute "comprising" (see line 2) with --comprises--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4, 10, 11, and 12-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a. Regarding claim 4, newly added limitation "said crimp being selectively biased against a portion of said flexible filament relative to said bone fixation element" (see lines 29-30) was not disclosed, described, or suggested in the specification and/or Figures. Claims 10 and 11 depend on claim 4.
- b. Regarding claim 12, the limitation "the crimp being selectively biased against the cannulated screw so as to fix a portion of the flexible filament relative to the cannulated screw" (see lines 9-

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10) was not disclosed, described, or suggested in the specification and/or Figures. Claims 13-18 depend on claim 12.

Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem is corrected.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4, 10, 11, 13-18, and 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 4, the limitation “selectively biased” (see line 29) is vague and confusing rendering the claim indefinite. “Selectively” in terms of what? Claims 10 and 11 depend on claim 4.
- b. Regarding claim 12, the limitation “selectively biased” (see line 9) is vague and confusing rendering the claim indefinite. “Selectively” in terms of what? Claims 13-18 depend on claim 4.
- c. Regarding claim 20, “the step of drilling” (see lines 1-2) lacks antecedent basis. Claims 21-26 depend on claim 20.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 2, 4, 6-9, 19-21, 23-26, and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chen et al. (US 4,773,910 A).

As seen in Figures 1-6, Chen et al. disclose a method for reconstructing a ligament comprising the steps of (i) forming a tunnel within a bone (see Figures), (ii) securing a bone fixation element (sleeves 30, 31, 32, 33) within the tunnel, a flexible filament (strands 10, 11) extending through a bore (see Figures) formed on the bone fixation element, (iii) securing a crimp (button 12) onto the flexible filament at a location spaced apart (see Figures 1-6) from the bone fixation element such that the crimp is securely fixed to the flexible filament independent of engagement between said crimp and said bone fixation element, and (iv) tensioning the flexible filament such that the crimp is biased against the bone fixation element (see Figure 1). It is inherent the use of a (endosteal) drill guide in order to precisely drill both bone tunnels.

13. Claims 19-21, 28, and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Legrand (US 5,456,721 A).

As seen in Figures 4 and 6, Legrand discloses a method for reconstructing a ligament comprising the steps of (i) forming a tunnel within a bone (see Figure 6: orifice 40), (ii) securing a bone fixation element (tube 5) within the tunnel, a flexible filament (see the extremity of sheath 1) extending through a bore (hole 53) formed on the bone fixation element, (iii) securing a crimp (either tube 7 shown in Figure 4, or, the knot shown in Figure 6) onto the flexible filament at a

location spaced apart (see Figures 4 and 6) from the bone fixation element such that the crimp is securely fixed to the flexible filament, (iv) securing a ligament (tendon 3) to the flexible filament, and (v) tensioning the flexible filament such that the crimp is biased against the bone fixation element (see column 3, lines 60-65). It is inherent the use of a (endosteal) drill guide in order to precisely drill both bone tunnels.

14. Claims 2, 4, and 6-10 are rejected, as best understood, under 35 U.S.C. 102(e) as being clearly anticipated by Chervitz et al. (US 6,283,996 B1).

As seen in Figures 7, 8A, and 8B, Chervitz et al. disclose an apparatus for reconstructing a ligament, said apparatus comprising (i) a bone fixation element (bone end 22) having a bore (holes 23a, 23b) and *adapted for* (emphasis added) positioning in a bone tunnel (tunnel section 50), (ii) a flexible filament (braided cable 46 formed by sutures 20) having retaining means (see loops) *for holding* (emphasis added) a graft ligament (ligament 21) and being slideably positioned through said bore of said bone fixation element (see Figures 7, 8A, and 8B), and (iii) a crimp (footing 48) crimped onto said flexible filament such that the crimp is securely fixed (see column 8, lines 45-59) to said flexible filament independent of engagement between said crimp and said bone fixation element (as shown in Figures 7, 8A, and 8B) and adjacent to a proximal end of said bone fixation element (see Figures 7, 8A, and 8B).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 5, 12-14, 18, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 4,773,910 A).

Chen et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing the bone fixation element (= sleeves 30, 31, 32, 33) as having a thread outwardly projecting from the bone fixation element. However, it is well known in the art the use of cannulated bone screws in order to secure a ligament graft to a bone tunnel. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified Chen et al. bone fixation element to have external threads since it is well known in the art the use of cannulated screws for securing a ligament graft to a bone tunnel.

Response to Arguments

17. Applicant's arguments with respect to claims 2 and 4 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

18. Claim 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Bowman et al. (US 4,950,270 A), Greenfield (US 5,584,835 A), Chervitz et al. (US 5,688,284 A), Chervitz et al. (US 5,766,250 A), McKernan et al. (US 6,066,173 A), and Simonian et al. (US 6,099,568 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



November 20, 2004



David H. Willse
Primary Examiner